

10/524094
DT01 Rec'd PCT/PTC 09 FEB 2005

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1 1. (original) A method for evaluating the HbA_{1c} of a patient based on BG data
2 collected over a first predetermined duration, said method comprising:
3 preparing the data for estimating HbA_{1c} using a predetermined sequence of
4 mathematical formulas defined as:
5 pre-processing of the data;
6 estimating HbA_{1c} using at least one of four predetermined formulas; and
7 validation of the estimate via sample selection criteria.

1 2. (original) The method of claim 1, wherein said first predetermined duration is
2 about 60 days.

1 3. (original) The method of claim 1, wherein said first predetermined duration
2 ranges from about 45 days to about 75 days.

1 4. (original) The method of claim 1, wherein said first predetermined duration
2 ranges from about 45 days to about 90 days.

1 5. (original) The method of claim 1, wherein the preprocessing of the data for each
2 patient comprise:
3 conversion of plasma to whole blood BG mg/dl;
4 conversion of BG measured in mg/dl to units of mmol/l; and
5 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
6 (RHI1).

1 6. (original) The method of claim 1, wherein the preprocessing of the data for each
2 patient using predetermined mathematical formulas defined as:
3 conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;
4 conversion of BG measured in mg/dl to units of mmol/l) via BGMM=BG/18; and

5 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
 6 (RHI1) using a predetermined mathematical formula defined as:
 7 $Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,
 8 $Risk1 = 22.765(Scale)^2$, wherein
 9 $RiskLO = Risk1$ if (BG is less than about 112.5) and therefore risk of LBGI
 10 exists, otherwise $RiskLO = 0$, and
 11 $RiskHI = Risk1$ if (BG is greater than about 112.5) and therefore risk of
 12 HBGI exists, otherwise $RiskHI = 0$,
 13 $BGMM1$ = average of BGMM per patient,
 14 $RLO1$ = average of RiskLO per patient,
 15 $RHI1$ = average of RiskHI per patient,
 16 $L06$ = average of RiskLO computed only for readings during the night, otherwise
 17 missing if there are no readings at night,
 18 $N06, N12, N24$ are percentage of SMBG readings in time intervals ,
 19 $NC1$ = total number of SMBG readings in the first predetermined duration; and
 20 $NDAYS$ = number of days with SMBG readings in the first predetermined
 21 duration.

1 7. (original) The method of claim 6, wherein the $N06, N12, N24$ are percentage of
 2 SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour
 3 time period, and about 18-23:59 hour time period, respectively.

1 8. (original) The method of claim 6, comprising assigning a group depending on
 2 the patient's computed High BG Index using a predetermined mathematical formula
 3 defined as:

4 if ($RHI1$ is \leq about 5.25 or if $RHI1$ is \geq about 16) then the assigned group= 0,
 5 if ($RHI1$ is $>$ about 5.25 and if $RHI1$ is $<$ about 7.0) then the assigned group=1,
 6 if ($RHI1$ is \geq about 7.0 and if $RHI1$ is $<$ about 8.5) then the assign group=2, and
 7 if ($RHI1$ is \geq about 8.5 and if $RHI1$ is $<$ about 16) then the assigned group=3.

1 9. (original) The method of claim 8, comprising providing estimates using a
2 predetermined mathematical formula defined as:

3 $E0 = 0.55555 * BGMM1 + 2.95,$

4 $E1 = 0.50567 * BGMM1 + 0.074 * L06 + 2.69,$

5 $E2 = 0.55555 * BGMM1 - 0.074 * L06 + 2.96,$

6 $E3 = 0.44000 * BGMM1 + 0.035 * L06 + 3.65;$ and

7 if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3)
8 then EST2=E3, otherwise EST2=E0.

1 10. (original) The method of claim 9, comprising providing further correction of
2 the estimates using a predetermined mathematical formula defined as:

3 if (missing(L06)) EST2=E0,

4 if (RLO1 is \leq about 0.5 and RHI1 is \leq about 2.0) then EST2=E0-0.25,

5 if (RLO1 is \leq about 2.5 and RHI1 is $>$ about 26) then EST2=E0-1.5*RLO1, and

6 if ((RLO1/RHI1) is \leq about 0.25 and L06 is $>$ about 1.3) then EST2=EST2-0.08.

1 11. (currently amended) The method of claim 10 for estimating the HbA_{1c} of a
2 patient based on BG data collected over the first predetermined duration, said method
3 comprising:

4 said estimating HbA_{1c} using said at least one of four predetermined mathematical
5 formulas defined as:

6 a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

7 b) HbA_{1c} = $0.809098 * BGMM1 + 0.064540 * RLO1 - 0.151673 * RHI1 +$
8 $1.873325,$ wherein

9 BGMM1 is the average BG (mmol/l) of claim 6.

10 RLO1 is the Low BG Index of claim 6.

11 RHI1 is the High BG Index of claim 6; or

12 c) HbA_{1c} = $0.682742 * HBA0 + 0.054377 * RHI1 + 1.553277,$ wherein

13 HBA0 is a previous reference HbA_{1c} reading taken about a second
14 predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 6; or

d) $HbA1c = 0.41046 * BGMM + 4.0775$

wherein BGMM1 is the average BG (mmol/l) of claim 6.

12. (original) The method of claim 11, wherein said second predetermined duration is about three months.

13. (original) The method of claim 11, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

14. (original) The method of claim 11, wherein said second predetermined duration ranges from about 2.5 months to six months.

15. (original) The method of claim 11, wherein the validation of the HbA1c estimate using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio $(RLO1/RHI1) \geq$ about 0.005),

wherein

RLO1 is the Low BG Index of claim 6

RHI1 is the High BG Index of claim 6; or

d) a randomness of data criterion-2 wherein HbA1c estimate is validated or displayed only if the ratio $(NO6 \geq$ about 3%).

16 wherein

17 N06 is the percentage of readings during the night of claim 6.

1 16. (original) The method of claim 15, wherein said third predetermined duration
2 is at least 35 days.

1 17. (original) The method of claim 15, wherein said third predetermined duration
2 ranges from about 35 days to about 40 days.

1 18. (original) The method of claim 15, wherein said third predetermined duration
2 ranges from about 35 days to about as long as the first predetermined duration.

1 19. (original) A system for evaluating the HbA_{1c} of a patient based on BG data
2 collected over a first predetermined duration, said system comprising:
3 a database component operative to maintain a database identifying said BG data;
4 and
5 a processor programmed to:
6 prepare the data for estimating HbA_{1c} using a predetermined sequence of
7 mathematical formulas defined as:
8 pre-process the data,
9 estimate HbA_{1c} using at least one of four predetermined formulas, and
10 validate the estimate via sample selection criteria.

1 20. (original) The system of claim 19, wherein said first predetermined duration is
2 about 60 days.

1 21. (original) The system of claim 19, wherein said first predetermined duration
2 ranges from about 45 days to about 75 days.

1 22. (original) The system of claim 19, wherein said first predetermined duration

2 ranges from about 45 days to about 90 days.

1 23. (original) The system of claim 19, wherein the preprocessing of the data for
2 each patient comprise:

3 conversion of plasma to whole blood BG mg/dl;
4 conversion of BG measured in mg/dl to units of mmol/l; and
5 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
6 (RHI1).

1 24. (original) The system of claim 19, wherein the preprocessing of the data for
2 each patient using predetermined mathematical formulas defined as:

3 conversion of plasma to whole blood BG mg/dl via $BG = PLASBG \text{ (mg/dl)} / 1.12$;
4 conversion of BG measured in mg/dl to units of mmol/l via $BGMM = BG / 18$; and
5 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
6 (RHI1) using a predetermined mathematical formula defined as:

7 $Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

8 $Risk1 = 22.765(Scale)^2$, wherein

9 $RiskLO = Risk1$ if (BG is less than about 112.5) and therefore risk of LBGI
10 exists, otherwise $RiskLO = 0$, and

11 $RiskHI = Risk1$ if (BG is greater than about 112.5) and therefore risk of
12 HBGI exists, otherwise $RiskHI = 0$,

13 $BGMM1 = \text{average of BGMM per patient}$,

14 $RLO1 = \text{average of RiskLO per patient}$,

15 $RHI1 = \text{average of RiskHI per patient}$,

16 $L06 = \text{average of RiskLO computed only for readings during the night, otherwise}$
17 $\text{missing if there are no readings at night}$,

18 $N06, N12, N24$ are percentage of SMBG readings in time intervals ,

19 $NC1 = \text{total number of SMBG readings in the first predetermined duration}$; and

20 $NDAYS = \text{number of days with SMBG readings in the first predetermined}$
21 duration .

1 25. (original) The system of claim 24, wherein the N06, N12, N24 are percentage
2 of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour
3 time period, and about 18-23:59 hour time period, respectively.

1 26. (original) The system of claim 24, comprising assigning a group depending on
2 the patient's computed High BG Index using a predetermined mathematical formula
3 defined as:

4 if (RHI1 is \leq about 5.25 or if RHI1 is \geq about 16) then the assigned group= 0,
5 if (RHI1 is $>$ about 5.25 and if RHI1 is $<$ about 7.0) then the assigned group=1,
6 if (RHI1 is \geq about 7.0 and if RHI1 is $<$ about 8.5) then the assign group=2, and
7 if (RHI1 is \geq about 8.5 and if RHI1 is $<$ about 16) then the assigned group=3.

1 27. (original) The system of claim 26, comprising providing estimates using a
2 predetermined mathematical formula defined as:

3 $E0 = 0.55555 * BGMM1 + 2.95,$

4 $E1 = 0.50567 * BGMM1 + 0.074 * L06 + 2.69,$

5 $E2 = 0.55555 * BGMM1 - 0.074 * L06 + 2.96,$

6 $E3 = 0.44000 * BGMM1 + 0.035 * L06 + 3.65;$ and

7 if (Group = 1) then $EST2 = E1$, or if (Group = 2) then $EST2 = E2$, or if (Group = 3)
8 then $EST2 = E3$, otherwise $EST2 = E0$.

1 28. (original) The system of claim 27, comprising providing further correction of
2 the estimates using a predetermined mathematical formula defined as:

3 if (missing(L06)) $EST2 = E0$,

4 if (RLO1 is \leq about 0.5 and RHI1 is \leq about 2.0) then $EST2 = E0 - 0.25$,

5 if (RLO1 is \leq about 2.5 and RHI1 is $>$ about 26) then $EST2 = E0 - 1.5 * RLO1$, and

6 if ((RLO1/RHI1) is \leq about 0.25 and L06 is $>$ about 1.3) then $EST2 = EST2 - 0.08$.

1 29. (currently amended) The system of claim 28 for estimating the HbA_{1c} of a

2 patient based on BG data collected over the first predetermined duration, said system
3 comprising:

4 said estimating HbA_{1c} using said at least one of four predetermined mathematical
5 formulas defined as:

6 a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

7 b) $HbA_{1c} = 0.809098 * BGMM1 + 0.064540 * RLO1 - 0.151673 * RHI1 +$
8 1.873325 , wherein

9 BGMM1 is the average BG (mmol/l) of claim 24,

10 RLO1 is the Low BG Index of claim 24,

11 RHI1 is the High BG Index of claim 24; or

12 c) $HbA_{1c} = 0.682742 * HBA0 + 0.054377 * RHI1 + 1.553277$, wherein

13 HBA0 is a previous reference HbA_{1c} reading taken about a second
14 predetermined period prior to the estimate, wherein

15 RHI1 = is the High BG Index of claim 24; or

16 d) $HbA_{1c} = 0.41046 * BGMM + 4.0775$

17 wherein BGMM1 is the average BG (mmol/l) of claim 24.

1 30. (original) The system of claim 29, wherein said second predetermined
2 duration is about three months.

1 31. (original) The system of claim 29, wherein said second predetermined
2 duration ranges from about 2.5 months to about 3.5 months.

1 32. (original) The system of claim 29, wherein said second predetermined
2 duration ranges from about 2.5 months to six months.

1 33. (currently amended) The system of claim 29, wherein the validation of the
2 HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first
3 predetermined duration sample meets at least one of the following four criteria:

- 4 a) a test frequency criterion wherein if the first predetermined duration
5 sample contains an average of at least about 1.5 to about 2.5 tests per day;
- 6 b) an alternative test frequency criterion only if the predetermined duration
7 sample contains at least a third predetermined sample period with readings with an
8 average frequency of about 1.8 readings/day;
- 9 c) a randomness of data criterion-1 wherein the HbA1c estimate is validated
10 or displayed only if the ratio $(RLO1/RHI1 \geq \text{about } 0.005)$,
- 11 wherein
- 12 RLO1 is the Low BG Index of claim 24,
13 RHI1 is the High BG Index of claim 24; or
- 14 d) a randomness of data criterion-2 wherein HbA1c estimate is validated or
15 displayed only if the ratio $(NO6 \geq \text{about } 3\%)$,
- 16 wherein
- 17 N06 is the percentage of readings during the night of claim 24.

1 34. (original) The system of claim 33, wherein said third predetermined duration
2 is at least 35 days.

1 35. (original) The system of claim 33, wherein said third predetermined duration
2 ranges from about 35 days to about 40 days.

1 36. (original) The system of claim 33, wherein said third predetermined duration
2 ranges from about 35 days to about as long as the first predetermined duration.

1 37. (original) A system for evaluating the HbA_{1c} of a patient based on BG data
2 collected over a first predetermined duration, said system comprising:
3 a BG acquisition mechanism, said acquisition mechanism configured to acquire
4 BG data from the patient;

5 a database component operative to maintain a database identifying said BG data;
6 and
7 a processor programmed to:
8 prepare the data for estimating HbA_{1c} using a predetermined sequence of
9 mathematical formulas defined as:
10 pre-process the data;
11 estimate HbA_{1c} using at least one of four predetermined formulas; and
12 validate the estimate via sample selection criteria.

1 38. (original) A computer program product comprising a computer useable
2 medium having computer program logic for enabling at least one processor in a computer
3 system to evaluate the HbA_{1c} of a patient based on BG data collected over a first
4 predetermined duration, said computer program logic comprising:
5 preparing the data for estimating HbA_{1c} using a predetermined sequence of
6 mathematical formulas defined as:
7 pre-processing of the data,
8 estimating HbA_{1c} using at least one of four predetermined formulas, and
9 validation of the estimate via sample selection criteria.

1 39. (original) The computer program product of claim 38, wherein said computer
2 program logic further comprises the steps of claim 11.

1 40. (original) A method for evaluating the long term probability for severe
2 hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data
3 collected over a predetermined duration, said method comprising:
4 computing LBG_I based on said collected BG data; and
5 estimating the number of future SH episodes using a predetermined mathematical
6 formula based on said computed LBG_I.

1 41. (original) The method of claim 40, wherein:

said computed LBGI is mathematically defined from a series of BG readings x_1, x_2, \dots, x_n taken at time points t_1, t_2, \dots, t_n as:

$$LBGI = \frac{1}{n} \sum_{i=1}^n lbgi(x_i; 2)$$

where:

$$lbgi(BG; a) = 10 \cdot f(BG)^a \text{ if } f(BG) > 0 \text{ and } 0 \text{ otherwise,}$$

$a = \text{about } 2$, representing a weighting parameter.

42. (original) The method of claim 40, further comprising:
defining predetermined risk categories(RCAT), each of said risk categories(RCAT) representing a range of values for LBGI; and
assigning said LBGI to at least one of said risk categories(RCAT).

43. (original) The method of claim 42, wherein said risk categories(RCAT) are defined as follows:

category 1, wherein said LBGI is less than about 0.25;
category 2, wherein said LBGI is between about 0.25 and about 0.50;
category 3, wherein said LBGI is between about 0.50 and about 0.75;
category 4, wherein said LBGI is between about 0.75 and about 1.0;
category 5, wherein said LBGI is between about 1.0 and about 1.25;
category 6, wherein said LBGI is between about 1.25 and about 1.50;
category 7, wherein said LBGI is between about 1.5 and about 1.75;
category 8, wherein said LBGI is between about 1.75 and about 2.0;
category 9, wherein said LBGI is between about 2.0 and about 2.5;
category 10, wherein said LBGI is between about 2.5 and about 3.0;
category 11, wherein said LBGI is between about 3.0 and about 3.5;
category 12, wherein said LBGI is between about 3.5 and about 4.25;
category 13, wherein said LBGI is between about 4.25 and about 5.0;
category 14, wherein said LBGI is between about 5.0 and about 6.5; and
category 15, wherein said LBGI is above about 6.5.

1 44. (original) The method of claim 42, further comprising:
2 defining a probability of incurring a select number of SH episodes respectively for
3 each of said assigned risk categories(RCAT).

1 45. (currently amended) The method of claim 42, further comprising:
2 defining a probability of incurring a select number of SH episodes within a next
3 first predetermined duration respectively for each of said assigned risk categories(RCAT),
4 using the formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:
6 a = about -4.19,
7 b = about 1.75

1 46. (original) The method of claim 45, wherein said first predetermined duration is
2 about one month.

1 47. (original) The method of claim 45, wherein said first predetermined duration
2 ranges from about 0.5 months to about 1.5 months.

1 48. (original) The method of claim 45, wherein said first predetermined duration
2 ranges from about 0.5 months to about 3 months.

1 49. (currently amended) The method of claim 42, further comprising:
2 defining a probability of incurring a select number of SH episodes within a next
3 second predetermined duration respectively for each of said assigned risk
4 categories(RCAT), using the formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:
6 a = about -3.28,
7 b = about 1.50,

1 50. (original) The method of claim 49, wherein said second predetermined

2 duration is about three months.

1 51. (original) The method of claim 49, wherein said second predetermined
2 duration ranges from about 2 months to about 4 months.

1 52. (original) The method of claim 49, wherein said second predetermined
2 duration ranges from about 3 months to about 6 months.

1 53. (currently amended) The method of claim 42, further comprising:
2 defining a probability of incurring a select number of SH episodes within the next
3 third predetermined duration respectively for each of said assigned risk
4 categories(RCAT), using the formula:

5 $F(x) = 1 - \exp(-a \cdot x^b)$ for any $x > 0$ and 0 otherwise, wherein:

6 | a = about -3.06,

7 b = about 1.45.

1 54. (original) The method of claim 53, wherein said third predetermined duration
2 is about 6 months.

1 55. (original) The method of claim 53, wherein said third predetermined duration
2 ranges from about 5 months to about 7 months.

1 56. (original) The method of claim 53, wherein said third predetermined duration
2 ranges from about 3 months to about 9 months.

1 57. (currently amended) The method of claim 42, further comprising:
2 defining a probability of incurring a select number of MH episodes within the next
3 month respectively for each of said assigned risk categories(RCAT), using the formula:

4 $F(x) = 1 - \exp(-a \cdot x^b)$ for any $x > 0$ and 0 otherwise, wherein:

5 | a = about -1.58,

6 b = about 1.05.

1 58. (currently amended) The method of claim 42, further comprising:
2 defining a probability of incurring a select number of MH episodes within the next
3 3 months respectively for each of said assigned risk categories(RCAT), using the
4 formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:
6 a = about -1.37,
7 b = about 1.14.

1 59. (currently amended) The method of claim 42, further comprising:
2 defining a probability of incurring a select number of MH episodes within the next
3 6 months respectively for each of said assigned risk categories(RCAT), using the
4 formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:
6 a = about -1.37,
7 b = about 1.35.

1 60. (original) The method of claim 40, further comprising:
2 assigning classifications of risk for future significant hypoglycemia of the patient.

1 61. (original) The method of claim 60, wherein said classifications are defined as
2 follows:
3 minimal risk, wherein said LBGI is less than about 1.25;
4 low risk, wherein said LBGI is between about 1.25 and about 2.50;
5 moderate risk, wherein said LBGI is between about 2.5 and about 5; and
6 high risk, wherein said LBGI is above about 5.0.

1 62. (original) A system for evaluating the long term probability for severe
2 hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data

collected over a predetermined duration, said system comprising:

- a database component operative to maintain a database identifying said BG data;
- and
- a processor programmed to:
 - compute LBGI based on said collected BG data, and
 - estimate the number of future SH episodes using a predetermined mathematical formula based on said computed LBGI.

63. (original) The method of claim 62, wherein:

said computed LBGI is mathematically defined from a series of BG readings x_1, x_2, \dots, x_n taken at time points t_1, t_2, \dots, t_n as:

$$LBGI = \frac{1}{n} \sum_{i=1}^n lbgi(x_i; 2)$$

where:

$$lbgi(BG; a) = 10 \cdot f(BG)^a \text{ if } f(BG) > 0 \text{ and } 0 \text{ otherwise,}$$

$a = \text{about } 2$, representing a weighting parameter.

64. (original) The system of claim 62, further comprising:

- defining predetermined risk categories(RCAT), each of said risk categories(RCAT) representing a range of values for LBGI; and
- assigning said LBGI to at least one of said risk categories(RCAT).

65. (original) The system of claim 64, wherein said risk categories (RCAT) are defined as follows:

- category 1, wherein said LBGI is less than about 0.25;
- category 2, wherein said LBGI is between about 0.25 and about 0.50;
- category 3, wherein said LBGI is between about 0.50 and about 0.75;
- category 4, wherein said LBGI is between about 0.75 and about 1.0;
- category 5, wherein said LBGI is between about 1.0 and about 1.25;
- category 6, wherein said LBGI is between about 1.25 and about 1.50;

category 7, wherein said LBGI is between about 1.5 and about 1.75;
category 8, wherein said LBGI is between about 1.75 and about 2.0;
category 9, wherein said LBGI is between about 2.0 and about 2.5;
category 10, wherein said LBGI is between about 2.5 and about 3.0
category 11, wherein said LBGI is between about 3.0 and about 3.5;
category 12, wherein said LBGI is between about 3.5 and about 4.25;
category 13, wherein said LBGI is between about 4.25 and about 5.0;
category 14, wherein said LBGI is between about 5.0 and about 6.5; and
category 15, wherein said LBGI is above about 6.5.

66. (original) The system of claim 64, further comprising:
defining a probability of incurring a select number of SH episodes respectively for
each of said assigned risk categories (RCAT).

67. (currently amended) The system of claim 64, further comprising:
defining a probability of incurring a select number of SH episodes within a next
first predetermined duration respectively for each of said assigned risk categories(RCAT),
using the formula:

$$F(x) = 1 - \exp(-a \cdot x^b) \text{ for any } x > 0 \text{ and } 0 \text{ otherwise, wherein:}$$

$$a = \text{about } -4.19,$$

$$b = \text{about } 1.75.$$

68. (original) The system of claim 67, wherein said first predetermined duration is
about one month.

69. (original) The system of claim 67, wherein said first predetermined duration
ranges from about 0.5 months to about 1.5 months.

70. (original) The system of claim 67, wherein said first predetermined duration
ranges from about 0.5 months to about 3 months.

1 71. (currently amended) The system of claim 64, further comprising:
2 defining a probability of incurring a select number of SH episodes within a next
3 second predetermined duration respectively for each of said assigned risk
4 categories(RCAT), using the formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:

6 a = about -3.28,

7 b = about 1.50.

1 72. (original) The system of claim 71, wherein said second predetermined
2 duration is about three months.

1 73. (original) The system of claim 71, wherein said second predetermined
2 duration ranges from about 2 months to about 4 months.

1 74. (original) The system of claim 71, wherein said second predetermined
2 duration ranges from about 3 months to about 6 months.

1 75. (currently amended) The system of claim 64, further comprising:
2 defining a probability of incurring a select number of SH episodes within the next
3 third predetermined duration respectively for each of said assigned risk
4 categories(RCAT), using the formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:

6 a = about -3.06,

7 b = about 1.45.

1 76. (original) The system of claim 75, wherein said third predetermined duration
2 is about 6 months.

1 77. (original) The system of claim 75, wherein said third predetermined duration
2 ranges from about 5 months to about 7 months.

1 78. (original) The system of claim 75, wherein said third predetermined duration
2 ranges from about 3 months to about 9 months.

1 79. (currently amended) The system of claim 64, further comprising:
2 defining a probability of incurring a select number of MH episodes within the next
3 month respectively for each of said assigned risk categories(RCAT), using the formula:

4 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:

5 a = about -1.58,

6 b = about 1.05.

1 80. (currently amended) The system of claim 64, further comprising:
2 defining a probability of incurring a select number of MH episodes within the next
3 3 months respectively for each of said assigned risk categories(RCAT), using the
4 formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:

6 a = about -1.37,

7 b = about 1.14.

1 81. (currently amended) The system of claim 64, further comprising:
2 defining a probability of incurring a select number of MH episodes within the next
3 6 months respectively for each of said assigned risk categories(RCAT), using the
4 formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:

6 a = about -1.37,

7 b = about 1.35.

1 82. (original) The system of claim 62, further comprising:
2 assigning classifications of risk for future significant hypoglycemia of the patient.

1 83. (original) The system of claim 82, wherein said classifications are defined as

2 follows:

- 3 minimal risk, wherein said LBGI is less than about 1.25;
- 4 low risk, wherein said LBGI is between about 1.25 and about 2.50;
- 5 moderate risk, wherein said LBGI is between about 2.5 and about 5; and
- 6 high risk, wherein said LBGI is above about 5.0.

1 84. (original) A system for evaluating the long term probability for severe
2 hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data
3 collected over a predetermined duration, said system comprising:

- 4 a BG acquisition mechanism, said acquisition mechanism configured to acquire
- 5 BG data from the patient;
- 6 a database component operative to maintain a database identifying said BG data;
- 7 and
- 8 a processor programmed to:
 - 9 compute LBGI based on said collected BG data, and
 - 10 estimate the number of future SH episodes using a predetermined
 - 11 mathematical formula based on said computed LBGI.

1 85. (original) A computer program product comprising a computer useable
2 medium having computer program logic for enabling at least one processor in a computer
3 system to evaluate the long term probability for severe hypoglycemia (SH) and/or
4 moderate hypoglycemia (MH) of a patient based on BG data collected over a
5 predetermined duration, said computer program logic comprising:

- 6 computing LBGI based on said collected BG data; and
- 7 estimating the number of future SH episodes using a predetermined mathematical
- 8 formula based on said computed LBGI.

1 86. (original) The computer program product of claim 85, wherein said computer
2 program logic further comprises the steps of claim 42.

1 87. (original) A method for evaluating the short term probability for severe
 2 hypoglycemia (SH) of a patient based on BG data collected over a predetermined
 3 duration, said method comprising:

4 computing scale values based on said collected BG data; and
 5 computing the low BG risk value (RLO) for each BG data.

1 88. (original) The method of claim 87, wherein:

2 said computed RLO(BG) is mathematically defined as:

3 $\text{Scale} = [\ln(\text{BG})]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl

4 $\text{Risk} = 22.765(\text{Scale})^2$

5 if (BG is less than about 112.5) then:

6 $\text{RLO}(\text{BG}) = \text{Risk}$, otherwise

7 $\text{RLO}(\text{BG}) = 0$.

1 89. (original) The method of claim 87, wherein:

2 said computed RLO(BG) is mathematically defined as:

3 $\text{Scale} = [\ln(\text{BG})]^{1.026} - 1.861$, wherein BG is measured in units of mmol/l

4 $\text{Risk} = 32.184(\text{Scale})^2$

5 if (BG is \leq about 112.5) then:

6 $\text{RLO}(\text{BG}) = \text{Risk}$, otherwise

7 $\text{RLO}(\text{BG}) = 0$.

1 90. (original) The method of claim 87, wherein:

2 computing LBGI based on said collected BG data, said computed LBGI is
 3 mathematically defined from a series of BG readings x_1, x_2, \dots, x_n taken at time points $t_1, t_2,$
 4 \dots, t_n as:

$$5 \quad \text{LBGI} = \frac{1}{n} \sum_{i=1}^n \text{lbgi}(x_i; 2)$$

6 where:

7 $\text{lbgi}(\text{BG}; a) = \text{RLO}(\text{BG})$.

1 91. (original) The method of claim 87, wherein:
 2 computing provisional LBGI based on said collected BG data, said computed provisional
 3 LBGI is mathematically defined from mathematically defined as:

$$4 \quad \text{LBGI}(1) = \text{RLO}(x_1)$$

$$5 \quad \text{RLO2}(1) = 0$$

$$6 \quad \text{LBGI}(j) = ((j-1)/j) * \text{LBGI}(j-1) + (1/j) * \text{RLO}(x_j)$$

$$7 \quad \text{RLO2}(j) = ((j-1)/j) * \text{RLO2}(j-1) + (1/j) * (\text{RLO}(x_j) - \text{LBGI}(j))^2.$$

1 92. (original) The method of claim 91, wherein:
 2 computing SBGI, said computed SBGI is mathematically defined as:

$$3 \quad \text{SBGI}(n) = \sqrt{\text{RLO2}(n)}.$$

1 93. (original) The method of claim 92, comprising qualifying or providing a
 2 warning of upcoming short term SH wherein if:

3 $(\text{LBGI}(150) \geq 2.5 \text{ and } \text{LBGI}(50) \geq (1.5 * \text{LBGI}(150) \text{ and } \text{SBGI}(50) \geq$
 4 $\text{SBGI}(150))$ then said issue of warning is qualified or provided, or

5 $\text{RLO} \geq (\text{LBGI}(150) + 1.5 * \text{SBGI}(150))$ then said issue of warning is
 6 qualified or provided;

7 otherwise:

8 a warning is not necessarily qualified or provided.

1 94. (original) The method of claim 92, comprising qualifying or providing a
 2 warning of upcoming short term SH wherein if:

3 $(\text{LBGI}(n) \geq \alpha \text{ and } \text{SBGI}(n) \geq \beta)$ then said issue of warning is qualified
 4 or provided, and/or

5 $(\text{RLO}(n) \geq (\text{LBGI}(n) + \gamma * \text{SBGI}(n)))$ then said issue of warning is qualified
 6 or provided;

7 otherwise:

8 a warning is not necessarily qualified or provided, wherein α , β , and γ are

9 threshold parameters.

1 95. (original) The method of claim 94, wherein said threshold parameters α , β ,
2 and γ are defined as α = about 5, β = about 7.5, γ = about 1.5.

1 96. (original) The method of claim 94, wherein said threshold parameters α , β ,
2 and γ are defined as any combination in a, b, and/or c, or as any intermediate combination
3 of values of said parameters between the values of said parameters in a, b, and/or c below:

4 a) α = 6.4, β = 8.2, γ = 1.5, α = 5.0, β = 7.5, γ = 1.3;

5 b) α = 6.0, β = 7.5, γ = 1.5, α = 4.9, β = 7.0, γ = 1.2; and/or

6 c) α = 5.5, β = 7.5, γ = 1.5, α = 4.8, β = 7.0, γ = 1.2.

1 97. (original) The method of claim 94, wherein said threshold parameters α , β ,
2 and γ are defined as any combination in a, b, and/or c, or as any intermediate combination
3 of values of said parameters between the values of said parameters in a, b, and/or c below:

4 a). α about 6.4, β about 8.2, γ about 1.5, α about 5.0, β about 7.5, γ about 1.3;

5 b). α about 6.0, β about 7.5, γ about 1.5, α about 4.9, β about 7.0, γ about 1.2;

6 and/or

7 c). α about 5.5, β about 7.5, γ about 1.5, α about 48, β about 7.0, γ about 1.2.

1 98. (original) A system for evaluating the short term probability for severe
2 hypoglycemia (SH) of a patient based on BG data collected over a predetermined
3 duration, said system comprising:

4 a database component operative to maintain a database identifying said BG data;

5 and

6 a processor programmed to:

7 compute scale values based on said collected BG data; and

8 compute the low BG risk value (RLO) for each BG data.

1 99. (original) The system of claim 98, wherein:

2 said computed $RLO(BG)$ is mathematically defined as:

3 $Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl

4 $Risk = 22.765(Scale)^2$

5 if (BG is less than about 112.5) then:

6 $RLO(BG) = Risk$, otherwise

7 $RLO(BG) = 0$.

1 100. (original) The system of claim 98, wherein:

2 said computed $RLO(BG)$ is mathematically defined as:

3 $Scale = [\ln(BG)]^{1.026} - 1.861$, wherein BG is measured in units of mmol/l

4 $Risk = 32.184(Scale)^2$

5 if (BG is \leq about 112.5) then:

6 $RLO(BG) = Risk$, otherwise

7 $RLO(BG) = 0$.

1 101. (original) The system of claim 98, wherein:

2 computing $LBGI$ based on said collected BG data, said computed $LBGI$ is

3 mathematically defined from a series of BG readings x_1, x_2, \dots, x_n taken at time points $t_1, t_2,$
4 \dots, t_n as:

$$5 \quad LBGI = \frac{1}{n} \sum_{i=1}^n lbgi(x_i; 2)$$

6 where:

$$7 \quad lbgi(BG; a) = RLO(BG).$$

1 102. (original) The system of claim 98, wherein:

2 computing provisional $LBGI$ based on said collected BG data, said computed provisional
3 $LBGI$ is mathematically defined from mathematically defined as:

$$4 \quad LBGI(1) = RLO(x_1)$$

$$5 \quad RLO2(1) = 0$$

$$\begin{aligned} \text{LBGI}(j) &= ((j-1)/j) * \text{LBGI}(j-1) + (1/j) * \text{RLO}(x_j) \\ \text{RLO2}(j) &= ((j-1)/j) * \text{RLO2}(j-1) + (1/j) * (\text{RLO}(x_j) - \text{LBGI}(j))^2. \end{aligned}$$

103. (original) The system of claim 102, wherein:
 computing SBGI, said computed SBGI is mathematically defined as:

$$\text{SBGI}(n) = \sqrt{(\text{RLO2}(n))}.$$

104. (original) The system of claim 103, comprising qualifying or providing a
 warning of upcoming short term SH wherein if:

$(\text{LBGI}(150) \geq 2.5 \text{ and } \text{LBGI}(50) \geq (1.5 * \text{LBGI}(150) \text{ and } \text{SBGI}(50) \geq$
 $\text{SBGI}(150))$ then said issue of warning is qualified or provided, or
 $\text{RLO} \geq (\text{LBGI}(150) + 1.5 * \text{SBGI}(150))$ then said issue of warning is
 qualified or provided;
 otherwise:

a warning is not necessarily qualified or provided.

105. (original) The system of claim 103, comprising qualifying or providing a
 warning of upcoming short term SH wherein if:

$(\text{LBGI}(n) \geq \alpha \text{ and } \text{SBGI}(n) \geq \beta)$ then said issue of warning is qualified
 or provided, and/or
 $(\text{RLO}(n) \geq (\text{LBGI}(n) + \gamma * \text{SBGI}(n)))$ then said issue of warning is qualified
 or provided;
 otherwise:

a warning is not necessarily qualified or provided, wherein α , β , and γ are
 threshold parameters.

106. (original) The system of claim 105, wherein said threshold parameters α , β ,
 and γ are defined as $\alpha = \text{about } 5$, $\beta = \text{about } 7.5$, $\gamma = \text{about } 1.5$.

107. (original) The system of claim 105, wherein said threshold parameters α , β , and γ are defined as any combination in a, b, and/or c, or as any intermediate combination of values of said parameters between the values of said parameters in a, b, and/or c below:

a) $\alpha = 6.4$, $\beta = 8.2$, $\gamma = 1.5$, $\alpha = 5.0$, $\beta = 7.5$, $\gamma = 1.3$;

b) $\alpha = 6.0$, $\beta = 7.5$, $\gamma = 1.5$, $\alpha = 4.9$, $\beta = 7.0$, $\gamma = 1.2$; and/or

c) $\alpha = 5.5$, $\beta = 7.5$, $\gamma = 1.5$, $\alpha = 4.8$, $\beta = 7.0$, $\gamma = 1.2$.

108. (original) The system of claim 105, wherein said threshold parameters α , β , and γ are defined as any combination in a, b, and/or c, or as any intermediate combination of values of said parameters between the values of said parameters in a, b, and/or c below:

a). α about 6.4, β about 8.2, γ about 1.5, α about 5.0, β about 7.5, γ about 1.3;

b). α about 6.0, β about 7.5, γ about 1.5, α about 4.9, β about 7.0, γ about 1.2;

and/or

c). α about 5.5, β about 7.5, γ about 1.5, α about 4.8, β about 7.0, γ about 1.2.

109. (original) A system for evaluating the short term probability for severe hypoglycemia (SH) of a patient based on BG data collected over a predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data;

and

a processor programmed to:

compute scale values based on said collected BG data; and

compute the low BG risk value (RLO) for each BG data.

110. (original) A computer program product comprising a computer useable medium having computer program logic for enabling at least one processor in a computer system to evaluating the short term probability for severe hypoglycemia (SH) of a patient

4 based on BG data collected over a predetermined duration, said computer program logic
5 comprising:

- 6 computing scale values based on said collected BG data; and
7 computing the low BG risk value (RLO) for each BG data.

1 111. (original) The computer program product of claim 110, wherein said
2 computer program logic further comprises the steps of claim 92.

1 112. (original) The method of claim 11, wherein the validation of the HbA1c
2 estimate using sample selection criteria of HbA1c estimate only if the first
3 predetermined duration sample meets at least one of the following four criteria:

4 a) a test frequency criterion wherein if the first predetermined duration
5 sample contains an average of at least about 1.5; and

6 b) a randomness of data criterion-1 wherein the HbA1c estimate is
7 validated or displayed only if the ratio $(RLO1/RHI1 \geq \text{about } 0.005)$;

8 wherein

9 RLO1 is the Low BG Index of claim 6

10 RHI1 is the High BG Index of claim 6; or

11 c) a randomness of data criterion-2 wherein HbA1c estimate is validated
12 or displayed only if the ratio $(NO6 \geq \text{about } 3\%)$,

13 wherein

14 NO6 is the percentage of readings during the night of claim 6.

1 113. (original) The method of claim 112, wherein said third predetermined
2 duration is at least about 35 days.

1 114. (currently amended) The system of claim 29, wherein the validation of
2 the HbA1c estimate using sample selection criteria of HbA1c estimate only if the first

predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio ($RLO1/RHI1 \geq$ about 0.005),

wherein

RLO1 is the Low BG Index of claim 624

RHI1 is the High BG Index of claim 624; or

c) a randomness of data criterion-2 wherein HbA1c estimate is validated or displayed only if the ratio ($NO6 \geq$ about 3%),

wherein

N06 is the percentage of readings during the night of claim 624.

115. (original) The system of claim 114, wherein said third predetermined duration is at least about 35 days.

116. (new) The system of claim 37, wherein said first predetermined duration is about 60 days.

117. (new) The system of claim 37, wherein said first predetermined duration ranges from about 45 days to about 75 days.

118. (new) The system of claim 37, wherein said first predetermined duration ranges from about 45 days to about 90 days.

119. (new) The system of claim 37, wherein the preprocessing of the data for each patient comprise:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

5 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
6 (RHI1).

1 120. (new) The system of claim 37, wherein the preprocessing of the data for each
2 patient using predetermined mathematical formulas defined as:

3 conversion of plasma to whole blood BG mg/dl via $BG = PLASBG \text{ (mg/dl)} / 1.12$;

4 conversion of BG measured in mg/dl to units of mmol/l via $BGMM = BG / 18$; and

5 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
6 (RHI1) using a predetermined mathematical formula defined as:

7 $Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

8 $Risk1 = 22.765(Scale)^2$, wherein

9 $RiskLO = Risk1$ if (BG is less than about 112.5) and therefore risk of LBGI
10 exists, otherwise $RiskLO = 0$, and

11 $RiskHI = Risk1$ if (BG is greater than about 112.5) and therefore risk of
12 HBGI exists, otherwise $RiskHI = 0$,

13 $BGMM1 = \text{average of BGMM per patient}$,

14 $RLO1 = \text{average of RiskLO per patient}$,

15 $RHI1 = \text{average of RiskHI per patient}$,

16 $L06 = \text{average of RiskLO computed only for readings during the night, otherwise}$
17 $\text{missing if there are no readings at night}$,

18 $N06, N12, N24$ are percentage of SMBG readings in time intervals ,

19 $NC1 = \text{total number of SMBG readings in the first predetermined duration}$; and

20 $NDAYS = \text{number of days with SMBG readings in the first predetermined}$
21 duration .

1 121. (new) The system of claim 120, wherein the $N06, N12, N24$ are percentage
2 of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour
3 time period, and about 18-23:59 hour time period, respectively.

1 122. (new) The system of claim 120, comprising assigning a group depending on

2 the patient's computed High BG Index using a predetermined mathematical formula
3 defined as:

4 if (RHI1 is \leq about 5.25 or if RHI1 is \geq about 16) then the assigned group= 0,
5 if (RHI1 is $>$ about 5.25 and if RHI1 is $<$ about 7.0) then the assigned group=1,
6 if (RHI1 is \geq about 7.0 and if RHI1 is $<$ about 8.5) then the assign group=2, and
7 if (RHI1 is \geq about 8.5 and if RHI1 is $<$ about 16) then the assigned group=3.

1 123. (new) The system of claim 122, comprising providing estimates using a
2 predetermined mathematical formula defined as:

3 $E0 = 0.55555 \cdot BGMM1 + 2.95$,
4 $E1 = 0.50567 \cdot BGMM1 + 0.074 \cdot L06 + 2.69$,
5 $E2 = 0.55555 \cdot BGMM1 - 0.074 \cdot L06 + 2.96$,
6 $E3 = 0.44000 \cdot BGMM1 + 0.035 \cdot L06 + 3.65$; and
7 if (Group = 1) then $EST2 = E1$, or if (Group = 2) then $EST2 = E2$, or if (Group = 3)
8 then $EST2 = E3$, otherwise $EST2 = E0$.

1 124. (new) The system of claim 123, comprising providing further correction of
2 the estimates using a predetermined mathematical formula defined as:

3 if (missing(L06)) $EST2 = E0$,
4 if (RLO1 is \leq about 0.5 and RHI1 is \leq about 2.0) then $EST2 = E0 - 0.25$,
5 if (RLO1 is \leq about 2.5 and RHI1 is $>$ about 26) then $EST2 = E0 - 1.5 \cdot RLO1$, and
6 if ((RLO1/RHI1) is \leq about 0.25 and L06 is $>$ about 1.3) then $EST2 = EST2 - 0.08$.

1 125. (new) The system of claim 124 for estimating the HbA_{1c} of a patient based
2 on BG data collected over the first predetermined duration, said system comprising:
3 said estimating HbA_{1c} using said at least one of four predetermined mathematical
4 formulas defined as:

5 a) HbA_{1c} = the $EST2$ defined by claim 8 or as corrected by claim 10 or
6 b) $HbA_{1c} = 0.809098 \cdot BGMM1 + 0.064540 \cdot RLO1 - 0.151673 \cdot RHI1 +$
7 1.873325 , wherein

8 BGMM1 is the average BG (mmol/l) of claim 120,

9 RLO1 is the Low BG Index of claim 120,

10 RHI1 is the High BG Index of claim 120; or

11 c) $HbA1c = 0.682742 * HBA0 + 0.054377 * RHI1 + 1.553277$, wherein

12 HBA0 is a previous reference HbA1c reading taken about a second
13 predetermined period prior to the estimate, wherein

14 RHI1 = is the High BG Index of claim 120; or

15 d) $HbA1c = 0.41046 * BGMM + 4.0775$

16 wherein BGMM1 is the average BG (mmol/l) of claim 120.

1 126. (new) The system of claim 125, wherein said second predetermined duration
2 is about three months.

1 127. (new) The system of claim 125, wherein said second predetermined duration
2 ranges from about 2.5 months to about 3.5 months.

1 128. (new) The system of claim 125, wherein said second predetermined duration
2 ranges from about 2.5 months to six months.

1 129. (new) The system of claim 125, wherein the validation of the HbA1c
2 estimate using sample selection criteria of HbA1c estimate only if the first predetermined
3 duration sample meets at least one of the following four criteria:

4 a) a test frequency criterion wherein if the first predetermined duration
5 sample contains an average of at least about 1.5 to about 2.5 tests per day;

6 b) an alternative test frequency criterion only if the predetermined duration
7 sample contains at least a third predetermined sample period with readings with an
8 average frequency of about 1.8 readings/day;

9 c) a randomness of data criterion-1 wherein the HbA1c estimate is validated
10 or displayed only if the ratio $(RLO1/RHI1) \geq$ about 0.005),

11 wherein
12 RLO1 is the Low BG Index of claim 120,
13 RHI1 is the High BG Index of claim 120; or
14 d) a randomness of data criterion-2 wherein HbA1c estimate is validated or
15 displayed only if the ratio (NO6 \geq about 3%),

16 wherein
17 N06 is the percentage of readings during the night of claim 120.

1 130. (new) The system of claim 129, wherein said third predetermined duration is
2 at least 35 days.

1 131. (new) The system of claim 129, wherein said third predetermined duration
2 ranges from about 35 days to about 40 days.

1 132. (new) The system of claim 129, wherein said third predetermined duration
2 ranges from about 35 days to about as long as the first predetermined duration.

1 133. (new) The system of claim 125, wherein the validation of the HbA1c
2 estimate using sample selection criteria of HbA1c estimate only if the first
3 predetermined duration sample meets at least one of the following four criteria:

4 a) a test frequency criterion wherein if the first predetermined duration
5 sample contains an average of at least about 1.5; and

6 b) a randomness of data criterion-1 wherein the HbA1c estimate is
7 validated or displayed only if the ratio (RLO1/RHI1 \geq about 0.005),

8 wherein
9 RLO1 is the Low BG Index of claim 120
10 RHI1 is the High BG Index of claim 120; or

11 c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated
12 or displayed only if the ratio (N06 >= about 3%),

13 wherein

14 N06 is the percentage of readings during the night of claim 120.

1 134. (new) The system of claim 133, wherein said third predetermined
2 duration is at least about 35 days.

1 135. (new) A method for evaluating the HbA_{1c} of a patient based on BG data
2 collected over a first predetermined duration, said method comprising:

3 preparing the data for estimating HbA_{1c} using a predetermined sequence of
4 mathematical formulas defined as:

5 pre-processing of the data;

6 validation of a sample of the BG data via sample selection criteria; and

7 estimating HbA_{1c} if the sample is valid.

1 136. (new) The method of claim 135, wherein said first predetermined duration is
2 about 60 days.

1 137. (new) The method of claim 135, wherein said first predetermined duration
2 ranges from about 45 days to about 75 days.

1 138. (new) The method of claim 135, wherein said first predetermined duration
2 ranges from about 45 days to about 90 days.

1 139. (new) The method of claim 135, wherein the preprocessing of the data for
2 each patient comprise:

3 conversion of plasma to whole blood BG mg/dl;

4 conversion of BG measured in mg/dl to units of mmol/l; and

5 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index

6 (RHI1).

1 140. (new) The method of claim 135, wherein the preprocessing of the data for
 2 each patient using predetermined mathematical formulas defined as:
 3 conversion of plasma to whole blood BG mg/dl via $BG = PLASBG \text{ (mg/dl)} / 1.12$;
 4 conversion of BG measured in mg/dl to units of mmol/l via $BGMM = BG / 18$; and
 5 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
 6 (RHI1) using a predetermined mathematical formula defined as:
 7 $Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,
 8 $Risk1 = 22.765(Scale)^2$, wherein
 9 $RiskLO = Risk1$ if (BG is less than about 112.5) and therefore risk of LBGI
 10 exists, otherwise $RiskLO = 0$, and
 11 $RiskHI = Risk1$ if (BG is greater than about 112.5) and therefore risk of
 12 HBGI exists, otherwise $RiskHI = 0$,
 13 $BGMM1$ = average of BGMM per patient,
 14 $RLO1$ = average of RiskLO per patient,
 15 $RHI1$ = average of RiskHI per patient,
 16 $L06$ = average of RiskLO computed only for readings during the night, otherwise
 17 missing if there are no readings at night,
 18 $N06, N12, N24$ are percentage of SMBG readings in time intervals ,
 19 $NC1$ = total number of SMBG readings in the first predetermined duration; and
 20 $NDAYS$ = number of days with SMBG readings in the first predetermined
 21 duration.

1 141. (new) The method of claim 140, wherein the $N06, N12, N24$ are percentage
 2 of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour
 3 time period, and about 18-23:59 hour time period, respectively.

1 142. (new) The method of claim 140, comprising assigning a group depending on
 2 the patient's computed High BG Index using a predetermined mathematical formula

3 defined as:

4 if (RHI1 is \leq about 5.25 or if RHI1 is \geq about 16) then the assigned group= 0,
 5 if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,
 6 if (RHI1 is \geq about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and
 7 if (RHI1 is \geq about 8.5 and if RHI1 is < about 16) then the assigned group=3.

1 143. (new) The method of claim 142, comprising providing estimates using a
 2 predetermined mathematical formula defined as:

3 $E0 = 0.55555 \cdot BGMM1 + 2.95$,

4 $E1 = 0.50567 \cdot BGMM1 + 0.074 \cdot L06 + 2.69$,

5 $E2 = 0.55555 \cdot BGMM1 - 0.074 \cdot L06 + 2.96$,

6 $E3 = 0.44000 \cdot BGMM1 + 0.035 \cdot L06 + 3.65$; and

7 if (Group = 1) then $EST2 = E1$, or if (Group = 2) then $EST2 = E2$, or if (Group = 3)
 8 then $EST2 = E3$, otherwise $EST2 = E0$.

1 144. (new) The method of claim 143, comprising providing further correction of
 2 the estimates using a predetermined mathematical formula defined as:

3 if (missing(L06)) $EST2 = E0$,

4 if (RLO1 is \leq about 0.5 and RHI1 is \leq about 2.0) then $EST2 = E0 - 0.25$,

5 if (RLO1 is \leq about 2.5 and RHI1 is > about 26) then $EST2 = E0 - 1.5 \cdot RLO1$, and

6 if ((RLO1/RHI1) is \leq about 0.25 and L06 is > about 1.3) then $EST2 = EST2 - 0.08$.

1 145. (new) The method of claim 144 for estimating the HbA_{1c} of a patient based
 2 on BG data collected over the first predetermined duration, said method comprising:
 3 estimating HbA_{1c} using at least one of four predetermined mathematical formulas
 4 defined as:

5 a) HbA_{1c} = the $EST2$ defined by claim 8 or as corrected by claim 10 or

6 b) $HbA_{1c} = 0.809098 \cdot BGMM1 + 0.064540 \cdot RLO1 - 0.151673 \cdot RHI1 +$
 7 1.873325 , wherein

8 $BGMM1$ is the average BG (mmol/l) of claim 140.

9 RLO1 is the Low BG Index of claim 140.
10 RHI1 is the High BG Index of claim 140; or
11 c) $HbA1c = 0.682742 \cdot HBA0 + 0.054377 \cdot RHI1 + 1.553277$, wherein
12 HBA0 is a previous reference HbA1c reading taken about a second
13 predetermined period prior to the estimate, wherein
14 RHI1 = is the High BG Index of claim 140; or
15 d) $HbA1c = 0.41046 \cdot BGMM + 4.0775$
16 wherein BGMM1 is the average BG (mmol/l) of claim 140.

1 146. (new) The method of claim 145, wherein said second predetermined duration
2 is about three months.

1 147. (new) The method of claim 145, wherein said second predetermined duration
2 ranges from about 2.5 months to about 3.5 months.

1 148. (new) The method of claim 145, wherein said second predetermined duration
2 ranges from about 2.5 months to six months.

1 149. (new) The method of claim 145, wherein the validation of the sample using
2 sample selection criteria of HbA1c estimate only if the first predetermined duration
3 sample meets at least one of the following four criteria:

4 a) a test frequency criterion wherein if the first predetermined duration
5 sample contains an average of at least about 1.5 to about 2.5 tests per day;

6 b) an alternative test frequency criterion only if the predetermined duration
7 sample contains at least a third predetermined sample period with readings with an
8 average frequency of about 1.8 readings/day;

9 c) a randomness of data criterion-1 wherein the HbA1c estimate is validated
10 or displayed only if the ratio $(RLO1/RHI1 \geq \text{about } 0.005)$,

11 wherein

12 RLO1 is the Low BG Index of claim 140

13 RHI1 is the High BG Index of claim 140; or

14 d) a randomness of data criterion-2 wherein HbA1c estimate is validated or
15 displayed only if the ratio (NO6 \geq about 3%).

16 wherein

17 NO6 is the percentage of readings during the night of claim 140.

1 150. (new) The method of claim 149, wherein said third predetermined duration is
2 at least 35 days.

1 151. (new) The method of claim 149, wherein said third predetermined duration
2 ranges from about 35 days to about 40 days.

1 152. (new) The method of claim 149, wherein said third predetermined duration
2 ranges from about 35 days to about as long as the first predetermined duration.

1 153. (new) The method of claim 145, wherein the validation of the sample
2 using sample selection criteria of HbA1c estimate only if the first predetermined
3 duration sample meets at least one of the following four criteria:

4 a) a test frequency criterion wherein if the first predetermined duration
5 sample contains an average of at least about 1.5; and

6 b) a randomness of data criterion-1 wherein the HbA1c estimate is
7 validated or displayed only if the ratio (RLO1/RHI1 \geq about 0.005),

8 wherein

9 RLO1 is the Low BG Index of claim 149

10 RHI1 is the High BG Index of claim 140; or

11 c) a randomness of data criterion-2 wherein HbA1c estimate is validated
12 or displayed only if the ratio (NO6 \geq about 3%),

13 wherein

14 N06 is the percentage of readings during the night of claim 140.

1 154. (new) The method of claim 153, wherein said third predetermined
2 duration is at least about 35 days.

1 155. (new) A system for evaluating the HbA_{1c} of a patient based on BG data
2 collected over a first predetermined duration, said system comprising:
3 a database component operative to maintain a database identifying said BG data;
4 and
5 a processor programmed to:
6 prepare the data for estimating HbA_{1c} using a predetermined sequence of
7 mathematical formulas defined as:
8 pre-process the data,
9 validate a sample of the BG data via sample selection criteria, and
10 estimate HbA_{1c} if the sample is valid.

1 156. (new) The system of claim 155, wherein said first predetermined duration is
2 about 60 days.

1 157. (new) The system of claim 155, wherein said first predetermined duration
2 ranges from about 45 days to about 75 days.

1 158. (new) The system of claim 155, wherein said first predetermined duration
2 ranges from about 45 days to about 90 days.

1 159. (new) The system of claim 155, wherein the preprocessing of the data for
2 each patient comprise:
3 conversion of plasma to whole blood BG mg/dl;
4 conversion of BG measured in mg/dl to units of mmol/l; and
5 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index

6 (RHI1).

1 160. (new) The system of claim 155, wherein the preprocessing of the data for
2 each patient using predetermined mathematical formulas defined as:

3 conversion of plasma to whole blood BG mg/dl via $BG = PLASBG \text{ (mg/dl)} / 1.12$;

4 conversion of BG measured in mg/dl to units of mmol/l via $BGMM = BG / 18$; and

5 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index

6 (RHI1) using a predetermined mathematical formula defined as:

7 $Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

8 $Risk1 = 22.765(Scale)^2$, wherein

9 $RiskLO = Risk1$ if (BG is less than about 112.5) and therefore risk of LBGI
10 exists, otherwise $RiskLO = 0$, and

11 $RiskHI = Risk1$ if (BG is greater than about 112.5) and therefore risk of
12 HBGI exists, otherwise $RiskHI = 0$,

13 $BGMM1 = \text{average of BGMM per patient}$,

14 $RLO1 = \text{average of RiskLO per patient}$,

15 $RHI1 = \text{average of RiskHI per patient}$,

16 $L06 = \text{average of RiskLO computed only for readings during the night, otherwise}$
17 $\text{missing if there are no readings at night}$,

18 $N06, N12, N24$ are percentage of SMBG readings in time intervals ,

19 $NC1 = \text{total number of SMBG readings in the first predetermined duration}$; and

20 $NDAYS = \text{number of days with SMBG readings in the first predetermined}$
21 duration .

1 161. (new) The system of claim 160, wherein the N06, N12, N24 are percentage
2 of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour
3 time period, and about 18-23:59 hour time period, respectively.

1 162. (new) The system of claim 160, comprising assigning a group depending on
2 the patient's computed High BG Index using a predetermined mathematical formula

3 defined as:

4 if (RHI1 is \leq about 5.25 or if RHI1 is \geq about 16) then the assigned group= 0,
 5 if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,
 6 if (RHI1 is \geq about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and
 7 if (RHI1 is \geq about 8.5 and if RHI1 is < about 16) then the assigned group=3.

1 163. (new) The system of claim 162, comprising providing estimates using a
 2 predetermined mathematical formula defined as:

3 $E0 = 0.55555 \cdot BGMM1 + 2.95$,

4 $E1 = 0.50567 \cdot BGMM1 + 0.074 \cdot L06 + 2.69$,

5 $E2 = 0.55555 \cdot BGMM1 - 0.074 \cdot L06 + 2.96$,

6 $E3 = 0.44000 \cdot BGMM1 + 0.035 \cdot L06 + 3.65$; and

7 if (Group = 1) then $EST2 = E1$, or if (Group = 2) then $EST2 = E2$, or if (Group = 3)
 8 then $EST2 = E3$, otherwise $EST2 = E0$.

1 164. (new) The system of claim 163, comprising providing further correction of
 2 the estimates using a predetermined mathematical formula defined as:

3 if (missing(L06)) $EST2 = E0$,

4 if (RLO1 is \leq about 0.5 and RHI1 is \leq about 2.0) then $EST2 = E0 - 0.25$,

5 if (RLO1 is \leq about 2.5 and RHI1 is > about 26) then $EST2 = E0 - 1.5 \cdot RLO1$, and

6 if ((RLO1/RHI1) is \leq about 0.25 and L06 is > about 1.3) then $EST2 = EST2 - 0.08$.

1 165. (new) The system of claim 164 for estimating the HbA_{1c} of a patient based
 2 on BG data collected over the first predetermined duration, said system comprising:

3 estimating HbA_{1c} using at least one of four predetermined mathematical formulas
 4 defined as:

5 a) HbA_{1c} = the $EST2$ defined by claim 8 or as corrected by claim 10 or

6 b) $HbA_{1c} = 0.809098 \cdot BGMM1 + 0.064540 \cdot RLO1 - 0.151673 \cdot RHI1 +$
 7 1.873325 , wherein

8 $BGMM1$ is the average BG (mmol/l) of claim 160,

9 RLO1 is the Low BG Index of claim 160,
10 RHI1 is the High BG Index of claim 160; or
11 c) $HbA1c = 0.682742 \cdot HBA0 + 0.054377 \cdot RHI1 + 1.553277$, wherein
12 HBA0 is a previous reference HbA1c reading taken about a second
13 predetermined period prior to the estimate, wherein
14 RHI1 = is the High BG Index of claim 160; or
15 d) $HbA1c = 0.41046 \cdot BGMM + 4.0775$
16 wherein BGMM1 is the average BG (mmol/l) of claim 160.

1 166. (new) The system of claim 165, wherein said second predetermined duration
2 is about three months.

1 167. (new) The system of claim 165, wherein said second predetermined duration
2 ranges from about 2.5 months to about 3.5 months.

1 168. (new) The system of claim 165, wherein said second predetermined duration
2 ranges from about 2.5 months to six months.

1 169. (new) The system of claim 165, wherein the validation of the sample using
2 sample selection criteria of HbA1c estimate only if the first predetermined duration
3 sample meets at least one of the following four criteria:

4 a) a test frequency criterion wherein if the first predetermined duration
5 sample contains an average of at least about 1.5 to about 2.5 tests per day;

6 b) an alternative test frequency criterion only if the predetermined duration
7 sample contains at least a third predetermined sample period with readings with an
8 average frequency of about 1.8 readings/day;

9 c) a randomness of data criterion-1 wherein the HbA1c estimate is validated
10 or displayed only if the ratio $(RLO1/RHI1 \geq \text{about } 0.005)$,

11 wherein

12 RLO1 is the Low BG Index of claim 160,
13 RHI1 is the High BG Index of claim 160; or
14 d) a randomness of data criterion-2 wherein HbA1c estimate is validated or
15 displayed only if the ratio (NO6 \geq about 3%),
16 wherein
17 NO6 is the percentage of readings during the night of claim 160.

1 170. (new) The system of claim 169, wherein said third predetermined duration is
2 at least 35 days.

1 171. (new) The system of claim 169, wherein said third predetermined duration
2 ranges from about 35 days to about 40 days.

1 172. (new) The system of claim 169, wherein said third predetermined duration
2 ranges from about 35 days to about as long as the first predetermined duration.

1 173. (new) The system of claim 165, wherein the validation of the sample
2 using sample selection criteria of HbA1c estimate only if the first predetermined
3 duration sample meets at least one of the following four criteria:

4 a) a test frequency criterion wherein if the first predetermined duration
5 sample contains an average of at least about 1.5; and

6 b) a randomness of data criterion-1 wherein the HbA1c estimate is
7 validated or displayed only if the ratio (RLO1/RHI1 \geq about 0.005),

8 wherein

9 RLO1 is the Low BG Index of claim 160
10 RHI1 is the High BG Index of claim 160; or

11 c) a randomness of data criterion-2 wherein HbA1c estimate is validated
12 or displayed only if the ratio (NO6 \geq about 3%),

13 wherein

14 N06 is the percentage of readings during the night of claim 160.

1 174. (new) The system of claim 173, wherein said third predetermined
2 duration is at least about 35 days.

1 175. (new) A system for evaluating the HbA_{1c} of a patient based on BG data
2 collected over a first predetermined duration, said system comprising:
3 a BG acquisition mechanism, said acquisition mechanism configured to acquire
4 BG data from the patient;
5 a database component operative to maintain a database identifying said BG data;
6 and
7 a processor programmed to:
8 prepare the data for estimating HbA_{1c} using a predetermined sequence of
9 mathematical formulas defined as:
10 pre-process the data;
11 validate a sample of the BG data via sample selection criteria; and
12 estimate HbA_{1c} if the sample is valid.

1 176. (new) The system of claim 175, wherein said first predetermined duration is
2 about 60 days.

1 177. (new) The system of claim 175, wherein said first predetermined duration
2 ranges from about 45 days to about 75 days.

1 178. (new) The system of claim 175, wherein said first predetermined duration
2 ranges from about 45 days to about 90 days.

1 179. (new) The system of claim 175, wherein the preprocessing of the data for
2 each patient comprise:
3 conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and
 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
 (RHI1).

180. (new) The system of claim 175, wherein the preprocessing of the data for
 each patient using predetermined mathematical formulas defined as:

conversion of plasma to whole blood BG mg/dl via $BG = PLASBG \text{ (mg/dl)} / 1.12$;
 conversion of BG measured in mg/dl to units of mmol/l via $BGMM = BG / 18$; and
 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
 (RHI1) using a predetermined mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

$RiskLO = Risk1$ if (BG is less than about 112.5) and therefore risk of LBGI
 exists, otherwise $RiskLO = 0$, and

$RiskHI = Risk1$ if (BG is greater than about 112.5) and therefore risk of
 HBGI exists, otherwise $RiskHI = 0$,

$BGMM1$ = average of BGMM per patient,

$RLO1$ = average of RiskLO per patient,

$RHI1$ = average of RiskHI per patient,

$L06$ = average of RiskLO computed only for readings during the night, otherwise
 missing if there are no readings at night,

$N06, N12, N24$ are percentage of SMBG readings in time intervals ,

$NC1$ = total number of SMBG readings in the first predetermined duration; and

$NDAYS$ = number of days with SMBG readings in the first predetermined
 duration.

181. (new) The system of claim 180, wherein the $N06, N12, N24$ are percentage
 of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour
 time period, and about 18-23:59 hour time period, respectively.

1 182. (new) The system of claim 180, comprising assigning a group depending on
2 the patient's computed High BG Index using a predetermined mathematical formula
3 defined as:

4 if (RHI1 is \leq about 5.25 or if RHI1 is \geq about 16) then the assigned group= 0,
5 if (RHI1 is $>$ about 5.25 and if RHI1 is $<$ about 7.0) then the assigned group=1,
6 if (RHI1 is \geq about 7.0 and if RHI1 is $<$ about 8.5) then the assign group=2, and
7 if (RHI1 is \geq about 8.5 and if RHI1 is $<$ about 16) then the assigned group=3.

1 183. (new) The system of claim 182, comprising providing estimates using a
2 predetermined mathematical formula defined as:

3 $E0 = 0.55555 * BGMM1 + 2.95$,
4 $E1 = 0.50567 * BGMM1 + 0.074 * L06 + 2.69$,
5 $E2 = 0.55555 * BGMM1 - 0.074 * L06 + 2.96$,
6 $E3 = 0.44000 * BGMM1 + 0.035 * L06 + 3.65$; and
7 if (Group = 1) then $EST2 = E1$, or if (Group = 2) then $EST2 = E2$, or if (Group = 3)
8 then $EST2 = E3$, otherwise $EST2 = E0$.

1 184. (new) The system of claim 183, comprising providing further correction of
2 the estimates using a predetermined mathematical formula defined as:

3 if (missing(L06)) $EST2 = E0$,
4 if (RLO1 is \leq about 0.5 and RHI1 is \leq about 2.0) then $EST2 = E0 - 0.25$,
5 if (RLO1 is \leq about 2.5 and RHI1 is $>$ about 26) then $EST2 = E0 - 1.5 * RLO1$, and
6 if ((RLO1/RHI1) is \leq about 0.25 and L06 is $>$ about 1.3) then $EST2 = EST2 - 0.08$.

1 185. (new) The system of claim 184 for estimating the HbA_{1c} of a patient based
2 on BG data collected over the first predetermined duration, said system comprising:
3 estimating HbA_{1c} using at least one of four predetermined mathematical formulas
4 defined as:

5 a) HbA_{1c} = the $EST2$ defined by claim 8 or as corrected by claim 10 or
6 b) $HbA_{1c} = 0.809098 * BGMM1 + 0.064540 * RLO1 - 0.151673 * RHI1 +$

7 1.873325, wherein

8 BGMM1 is the average BG (mmol/l) of claim 180,

9 RLO1 is the Low BG Index of claim 180,

10 RHI1 is the High BG Index of claim 180; or

11 c) $HbA1c = 0.682742 * HBA0 + 0.054377 * RHI1 + 1.553277$, wherein

12 HBA0 is a previous reference HbA1c reading taken about a second
13 predetermined period prior to the estimate, wherein

14 RHI1 = is the High BG Index of claim 180; or

15 d) $HbA1c = 0.41046 * BGMM + 4.0775$

16 wherein BGMM1 is the average BG (mmol/l) of claim 180.

1 186. (new) The system of claim 185, wherein said second predetermined duration
2 is about three months.

1 187. (new) The system of claim 185, wherein said second predetermined duration
2 ranges from about 2.5 months to about 3.5 months.

1 188. (new) The system of claim 185, wherein said second predetermined duration
2 ranges from about 2.5 months to six months.

1 189. (new) The system of claim 185, wherein the validation of the sample using
2 sample selection criteria of HbA1c estimate only if the first predetermined duration
3 sample meets at least one of the following four criteria:

4 a) a test frequency criterion wherein if the first predetermined duration
5 sample contains an average of at least about 1.5 to about 2.5 tests per day;

6 b) an alternative test frequency criterion only if the predetermined duration
7 sample contains at least a third predetermined sample period with readings with an
8 average frequency of about 1.8 readings/day;

9 c) a randomness of data criterion-1 wherein the HbA1c estimate is validated
10 or displayed only if the ratio $(RLO1/RHI1 \geq \text{about } 0.005)$,

11 wherein

12 RLO1 is the Low BG Index of claim 180,

13 RHI1 is the High BG Index of claim 180; or

14 d) a randomness of data criterion-2 wherein HbA1c estimate is validated or
15 displayed only if the ratio $(NO6 \geq \text{about } 3\%)$,

16 wherein

17 NO6 is the percentage of readings during the night of claim 180.

1 190. (new) The system of claim 189, wherein said third predetermined duration is
2 at least 35 days.

1 191. (new) The system of claim 189, wherein said third predetermined duration
2 ranges from about 35 days to about 40 days.

1 192. (new) The system of claim 189, wherein said third predetermined duration
2 ranges from about 35 days to about as long as the first predetermined duration.

1 193. (new) The system of claim 185, wherein the validation of the sample
2 using sample selection criteria of HbA1c estimate only if the first predetermined
3 duration sample meets at least one of the following four criteria:

4 a) a test frequency criterion wherein if the first predetermined duration
5 sample contains an average of at least about 1.5; and

6 b) a randomness of data criterion-1 wherein the HbA1c estimate is
7 validated or displayed only if the ratio $(RLO1/RHI1 \geq \text{about } 0.005)$,

8 wherein

9 RLO1 is the Low BG Index of claim 180

10 RHI1 is the High BG Index of claim 180; or
11 c) a randomness of data criterion-2 wherein HbA1c estimate is validated
12 or displayed only if the ratio (NO6 \geq about 3%),
13 wherein
14 NO6 is the percentage of readings during the night of claim 180.

1 194. (new) The system of claim 193, wherein said third predetermined
2 duration is at least about 35 days.

1 195. (new) A method for evaluating the HbA_{1c} of a patient without the need for
2 prior HbA_{1c} information based on BG data collected over a first predetermined duration,
3 said method comprising:
4 preparing the data for estimating HbA_{1c} using a predetermined sequence of
5 mathematical formulas defined as:
6 pre-processing of the data;
7 validation of a sample of the BG data via sample selection criteria; and
8 estimating HbA_{1c} if the sample is valid.

1 196. (new) The method of claim 195, wherein said first predetermined duration is
2 about 60 days.

1 197. (new) The method of claim 195, wherein said first predetermined duration
2 ranges from about 45 days to about 75 days.

1 198. (new) The method of claim 195, wherein said first predetermined duration
2 ranges from about 45 days to about 90 days.

1 199. (new) The method of claim 195, wherein the preprocessing of the data for
2 each patient comprise:
3 conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and
 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
 (RHI1).

200 (new) The method of claim 195, wherein the preprocessing of the data for
 each patient using predetermined mathematical formulas defined as:

conversion of plasma to whole blood BG mg/dl via $BG = PLASBG \text{ (mg/dl)} / 1.12$;
 conversion of BG measured in mg/dl to units of mmol/l via $BGMM = BG / 18$; and
 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
 (RHI1) using a predetermined mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

$RiskLO = Risk1$ if (BG is less than about 112.5) and therefore risk of LBGI
 exists, otherwise $RiskLO = 0$, and

$RiskHI = Risk1$ if (BG is greater than about 112.5) and therefore risk of
 HBGI exists, otherwise $RiskHI = 0$,

$BGMM1 = \text{average of BGMM per patient}$,

$RLO1 = \text{average of RiskLO per patient}$,

$RHI1 = \text{average of RiskHI per patient}$,

$L06 = \text{average of RiskLO computed only for readings during the night, otherwise}$
 missing if there are no readings at night,

$N06, N12, N24$ are percentage of SMBG readings in time intervals ,

$NC1 = \text{total number of SMBG readings in the first predetermined duration; and}$

$NDAYS = \text{number of days with SMBG readings in the first predetermined}$
 duration.

201. (new) The method of claim 200, wherein the $N06, N12, N24$ are percentage
 of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour
 time period, and about 18-23:59 hour time period, respectively.

1 202. (new) The method of claim 200, comprising assigning a group depending on
 2 the patient's computed High BG Index using a predetermined mathematical formula
 3 defined as:

4 if (RHI1 is \leq about 5.25 or if RHI1 is \geq about 16) then the assigned group= 0,
 5 if (RHI1 is $>$ about 5.25 and if RHI1 is $<$ about 7.0) then the assigned group=1,
 6 if (RHI1 is \geq about 7.0 and if RHI1 is $<$ about 8.5) then the assign group=2, and
 7 if (RHI1 is \geq about 8.5 and if RHI1 is $<$ about 16) then the assigned group=3.

1 203. (new) The method of claim 202, comprising providing estimates using a
 2 predetermined mathematical formula defined as:

3 $E0 = 0.55555 \cdot BGMM1 + 2.95$,
 4 $E1 = 0.50567 \cdot BGMM1 + 0.074 \cdot L06 + 2.69$,
 5 $E2 = 0.55555 \cdot BGMM1 - 0.074 \cdot L06 + 2.96$,
 6 $E3 = 0.44000 \cdot BGMM1 + 0.035 \cdot L06 + 3.65$; and
 7 if (Group = 1) then $EST2 = E1$, or if (Group = 2) then $EST2 = E2$, or if (Group = 3)
 8 then $EST2 = E3$, otherwise $EST2 = E0$.

1 204. (new) The method of claim 203, comprising providing further correction of
 2 the estimates using a predetermined mathematical formula defined as:

3 if (missing(L06)) $EST2 = E0$,
 4 if (RLO1 is \leq about 0.5 and RHI1 is \leq about 2.0) then $EST2 = E0 - 0.25$,
 5 if (RLO1 is \leq about 2.5 and RHI1 is $>$ about 26) then $EST2 = E0 - 1.5 \cdot RLO1$, and
 6 if ((RLO1/RHI1) is \leq about 0.25 and L06 is $>$ about 1.3) then $EST2 = EST2 - 0.08$.

1 205. (new) The method of claim 204 for estimating the HbA_{1c} of a patient based
 2 on BG data collected over the first predetermined duration, said method comprising:
 3 estimating HbA_{1c} using at least one of four predetermined mathematical formulas
 4 defined as:

5 a) HbA_{1c} = the $EST2$ defined by claim 8 or as corrected by claim 10 or
 6 b) $HbA_{1c} = 0.809098 \cdot BGMM1 + 0.064540 \cdot RLO1 - 0.151673 \cdot RHI1 +$

1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 200,

RLO1 is the Low BG Index of claim 200,

RHI1 is the High BG Index of claim 200; or

c) $HbA1c = 0.682742 * HBA0 + 0.054377 * RHI1 + 1.553277$, wherein

HBA0 is a previous reference HbA1c reading taken about a second predetermined period prior to the estimate, wherein

RHI1 is the High BG Index of claim 200; or

d) $HbA1c = 0.41046 * BGMM + 4.0775$

wherein BGMM1 is the average BG (mmol/l) of claim 200.

206. (new) The method of claim 205, wherein said second predetermined duration is about three months.

207. (new) The method of claim 205, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

208. (new) The method of claim 205, wherein said second predetermined duration ranges from about 2.5 months to six months.

209. (new) The method of claim 205, wherein the validation of the sample using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

9 c) a randomness of data criterion-1 wherein the HbA1c estimate is validated
10 or displayed only if the ratio $(RLO1/RHI1 \geq \text{about } 0.005)$,

11 wherein

12 RLO1 is the Low BG Index of claim 200

13 RHI1 is the High BG Index of claim 200; or

14 d) a randomness of data criterion-2 wherein HbA1c estimate is validated or
15 displayed only if the ratio $(NO6 \geq \text{about } 3\%)$.

16 wherein

17 NO6 is the percentage of readings during the night of claim 200.

1 210. (new) The method of claim 209, wherein said third predetermined duration is
2 at least 35 days.

1 211. (new) The method of claim 209, wherein said third predetermined duration
2 ranges from about 35 days to about 40 days.

1 212. (new) The method of claim 209, wherein said third predetermined duration
2 ranges from about 35 days to about as long as the first predetermined duration.

1 213. (new) The method of claim 205, wherein the validation of the sample
2 using sample selection criteria of HbA1c estimate only if the first predetermined
3 duration sample meets at least one of the following four criteria:

4 a) a test frequency criterion wherein if the first predetermined duration
5 sample contains an average of at least about 1.5; and

6 b) a randomness of data criterion-1 wherein the HbA1c estimate is
7 validated or displayed only if the ratio $(RLO1/RHI1 \geq \text{about } 0.005)$,

8 wherein

9 RLO1 is the Low BG Index of claim 149

10 RHI1 is the High BG Index of claim 200; or

11 c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated
12 or displayed only if the ratio (NO6 \geq about 3%),

13 wherein

14 NO6 is the percentage of readings during the night of claim 200.

1 214. (new) The method of claim 213, wherein said third predetermined
2 duration is at least about 35 days.

1 215. (new) A system for evaluating the HbA_{1c} of a patient without the need for
2 prior HbA_{1c} information based on BG data collected over a first predetermined duration,
3 said system comprising:

4 a database component operative to maintain a database identifying said BG data;
5 and

6 a processor programmed to:

7 prepare the data for estimating HbA_{1c} using a predetermined sequence of
8 mathematical formulas defined as:

9 pre-process the data,

10 validate a sample of the BG data via sample selection criteria, and

11 estimate HbA_{1c} if the sample is valid.

1 216. (new) The system of claim 215, wherein said first predetermined duration is
2 about 60 days.

1 217. (new) The system of claim 215, wherein said first predetermined duration
2 ranges from about 45 days to about 75 days.

1 218. (new) The system of claim 215, wherein said first predetermined duration
2 ranges from about 45 days to about 90 days.

1 219. (new) The system of claim 215, wherein the preprocessing of the data for
2 each patient comprise:

3 conversion of plasma to whole blood BG mg/dl;
4 conversion of BG measured in mg/dl to units of mmol/l; and
5 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
6 (RHI1).

1 220. (new) The system of claim 215, wherein the preprocessing of the data for
2 each patient using predetermined mathematical formulas defined as:

3 conversion of plasma to whole blood BG mg/dl via $BG = PLASBG \text{ (mg/dl)} / 1.12$;
4 conversion of BG measured in mg/dl to units of mmol/l via $BGMM = BG / 18$; and
5 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
6 (RHI1) using a predetermined mathematical formula defined as:

7 $Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

8 $Risk1 = 22.765(Scale)^2$, wherein

9 $RiskLO = Risk1$ if (BG is less than about 112.5) and therefore risk of LBGI
10 exists, otherwise $RiskLO = 0$, and

11 $RiskHI = Risk1$ if (BG is greater than about 112.5) and therefore risk of
12 HBGI exists, otherwise $RiskHI = 0$,

13 $BGMM1$ = average of BGMM per patient,

14 $RLO1$ = average of RiskLO per patient,

15 $RHI1$ = average of RiskHI per patient,

16 $L06$ = average of RiskLO computed only for readings during the night, otherwise
17 missing if there are no readings at night,

18 $N06, N12, N24$ are percentage of SMBG readings in time intervals ,

19 $NC1$ = total number of SMBG readings in the first predetermined duration; and

20 $NDAYS$ = number of days with SMBG readings in the first predetermined
21 duration.

1 221. (new) A system for evaluating the HbA_{1c} of a patient without the need for

2 prior HbA_{1c} information based on BG data collected over a first predetermined duration,
3 said system comprising:

4 a BG acquisition mechanism, said acquisition mechanism configured to acquire
5 BG data from the patient;

6 a database component operative to maintain a database identifying said BG data;
7 and

8 a processor programmed to:

9 prepare the data for estimating HbA_{1c} using a predetermined sequence of
10 mathematical formulas defined as:

11 pre-process the data;

12 validate a sample of the BG data via sample selection criteria; and

13 estimate HbA_{1c} if the sample is valid.

1 222. (new) The system of claim 221, wherein said first predetermined duration is
2 about 60 days.

1 223. (new) The system of claim 221, wherein said first predetermined duration
2 ranges from about 45 days to about 75 days.

1 224. (new) The system of claim 221, wherein said first predetermined duration
2 ranges from about 45 days to about 90 days.

1 225. (new) The system of claim 221, wherein the preprocessing of the data for
2 each patient comprise:

3 conversion of plasma to whole blood BG mg/dl;

4 conversion of BG measured in mg/dl to units of mmol/l; and

5 computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index
6 (RHI1).

1 226. (new) The system of claim 221, wherein the preprocessing of the data for

each patient using predetermined mathematical formulas defined as:

conversion of plasma to whole blood BG mg/dl via $BG = PLASBG \text{ (mg/dl)} / 1.12$;

conversion of BG measured in mg/dl to units of mmol/l via $BGMM = BG / 18$; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index

(RHI1) using a predetermined mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

$RiskLO = Risk1$ if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise $RiskLO = 0$, and

$RiskHI = Risk1$ if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise $RiskHI = 0$,

$BGMM1$ = average of BGMM per patient,

$RLO1$ = average of RiskLO per patient,

$RHI1$ = average of RiskHI per patient,

$L06$ = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

$N06, N12, N24$ are percentage of SMBG readings in time intervals ,

$NC1$ = total number of SMBG readings in the first predetermined duration; and

$NDAYS$ = number of days with SMBG readings in the first predetermined duration.